

## REMARKS

Claims 1-15 and 17-40 were pending in the application prior to this amendment. No claims have been added or cancelled by this amendment.

### I. INTRODUCTION

Dental bleaching compositions that include potassium nitrate within the claimed amounts are believed to have surprising and unexpected properties compared to compositions that include different amounts of potassium nitrate. As evidenced by the comparative study described in the present application and in Preliminary Amendment "A", dental bleaching compositions that include potassium nitrate in an amount of about 0.01% to about 2% by weight, more preferably in a range of about 0.05% to about 1% by weight, and most preferably in an amount of about 0.5% by weight, possess the surprising and unexpected property of being able to better reduce the incidence of tooth sensitivity that is commonly experienced by users of dental bleaching products compared to dental bleaching compositions that include more potassium nitrate (*e.g.*, 3%).

This is entirely counterintuitive and contrary to what one would expect when including potassium nitrate as a desensitizing agent. Since potassium nitrate is a known desensitizing agent, one would expect that increasing the quantity of this component would incrementally increase its desensitizing effect. Indeed, the opposite has been found to be true: using a relatively small quantity of potassium nitrate (*e.g.*, 0.5%) actually *increases* its desensitization effect *vis-à-vis* the dental bleaching agent compared to using a greater amount (*e.g.*, 3%). Whereas at least two of the patents of record generally disclose the use of 0.1-10% by weight of a desensitizing agent (of which potassium nitrate is but one example from among several), none

provide any teaching or suggestion that would have motivated one of ordinary skill in the art to select the specific concentrations of potassium nitrate that are disclosed and claimed in the present application. Simply providing a single broad range of 0.1-10% does not, by itself, teach which specific concentrations within this broad range provide the best results. Moreover, one of ordinary skill would expect that including more potassium nitrate would provide greater desensitization. In fact, the comparative study indicates that this logical assumption is false and that including a relatively small amount of potassium nitrate works better to offset the sensitivity caused by the bleaching agent than using a greater amount. This is clearly a surprising and unexpected result.

Finally, the comparative study also indicates that, in at least some cases, the inventive dental bleaching compositions may provide greater whitening compared to bleaching compositions that include a different amount of potassium nitrate. Again, the fact that increased whitening was experienced at least some of the time when using the claimed quantities of potassium nitrate is further evidence of the inventiveness of the dental bleaching compositions disclosed and claimed herein.

## **II. REJECTION UNDER 35 U.S.C. § 103(a)**

The Office Action rejects claims 1-15 and 17-35 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,256,402 to Prencipe et al. In making this rejection, the Office Action alleges that Prencipe et al. discloses a dentifrice comprising a peroxide compound and potassium nitrate within a concentration of about 0.1 to about 10% by weight. Based on this, and in view of the fact that the claims in the present application describe an overlapping

concentration range for potassium nitrate, the Office Action alleges that the claims are *prima facie* obvious over Prencipe et al.

According to MPEP § 2144.05, under the heading entitled “I. OVERLAP OF RANGES”, “[i]n the case where the claimed ranges ‘overlap or lie inside ranges disclosed by the prior art’ a *prima facie* case of obviousness exists. *In re Werthheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990)”. However, under the subsequent heading within this same section entitled “III. REBUTTAL OF *PRIMA FACIE* CASE OF OBVIOUSNESS”, the MPEP states the following:

Applicants can rebut a *prima facie* case of obviousness based on overlapping ranges by showing the criticality of the claimed range. “The law is replete with cases in which the difference between the claimed invention and the prior art is some range or other variable within the claims.... In such a situation, the applicant must show that the particular range is critical, generally by showing that the claimed range achieves unexpected results relative to the prior art range.” *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990).

MPEP § 2144.05 (emphasis added).

Although a *prima facie* case of obviousness can hypothetically be made based on the fact that the concentration ranges for potassium nitrate in the instant claims overlap the single range disclosed in Prencipe et al. (*i.e.*, 0.1-10%), Applicants have provided sufficient evidence to rebut the *prima facie* case because the comparative study “show[s] the criticality of the claimed range[s]”. In particular, the comparative study demonstrates that using an amount of potassium nitrate within the claimed ranges (*e.g.*, 0.5%) results in a greater desensitization effect *vis-à-vis* the dental bleaching agent than using an amount of potassium nitrate outside the claimed ranges but still within the range disclosed in Prencipe et al. (*e.g.*, 3%). This is an unexpected result

because one of ordinary skill would expect 3% potassium nitrate to provide greater desensitization than 0.5% potassium nitrate, not less. In fact, including 3% potassium actually caused *greater* sensitivity and pain compared to 0.5% potassium nitrate. This is truly unexpected because potassium nitrate is known to be a desensitizing agent. One does not expect an ingredient to provide less of its desired property when increasing its concentration (*e.g.*, just like *decreasing* the amount of abrasive in the Prencipe et al. composition would not be expected to make the resulting dentifrice *more* abrasive, one would not expect that *decreasing* the amount of potassium nitrate would *increase* its desensitizing effect *vis-à-vis* the dental bleaching agent).

On this basis alone, each of the independent claims is patentable and unobvious over Prencipe et al. Accordingly, Applicants respectfully request the Examiner to acknowledge that the *prima facie* obviousness rejection has been rebutted by the comparative study and withdraw the rejection of the claims over Prencipe et al. on this basis alone.

Although Applicants do not admit that recently issued U.S. Patent No. 6,458,340 to Ibsen et al. is prior art to the invention described and claimed in the instant application, the foregoing analysis applies to this reference as well. Ibsen et al. discloses a dental bleaching composition that includes, among other things, a dental bleaching agent and a desensitizing agent that may be selected from among several apparently equivalent choices and included in an amount of about 0.1-10% by weight (the same range disclosed in Prencipe et al.). Because Ibsen et al., like Prencipe et al., neither teaches nor suggested a dental bleaching composition containing the optimal concentration of potassium nitrate as disclosed and claimed in the instant application, the claims are patentable and unobvious over Ibsen et al. for this reason alone. Thus, whereas one might allege that the claims are *prima facie* obvious over Ibsen et al. to the extent Ibsen et al. can be established as being prior art to the claimed invention, Applicants have already rebutted any

*prima facie* case of obviousness relative to Ibsen et al. by submitting the comparative study. Compared to the compositions disclosed in Ibsen et al., the dental bleaching compositions disclosed and claimed in the current application possess surprising and unexpected results, as discussed above. Thus, the claims are patentable and unobvious over the teachings disclosed in Ibsen et al. on this basis alone.

### **III. AMENDMENTS TO CLAIMS 17 AND 28**

Claims 17 and 28 have been amended to remove the requirement that including potassium nitrate in the claimed amount causes increased whitening. Whereas the claimed dental bleaching compositions have been shown to result in increased tooth whitening in at least some cases, this property is less important and ancillary to the ability of the claimed compositions to reduce tooth sensitivity. For this reason, claims 17 and 28 have been amended to omit the requirement that the claimed compositions provide greater whitening.

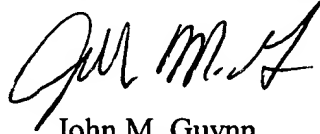
### **IV. CONCLUSION.**

Applicants believe that the present application is currently in allowable form. In the event the Examiner finds any remaining impediment to the prompt allowance of this application, which could be clarified by a telephonic interview, or which is susceptible to being overcome by means of an Examiner's Amendment, the Examiner is respectfully requested to initiate a telephonic interview with the undersigned attorney.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "VERSION WITH MARKINGS TO SHOW CHANGES MADE".

Dated this 8<sup>th</sup> day of January 2003.

Respectfully submitted,



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**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

**IN THE CLAIMS:**

Claims 17 and 28 and 29 have been amended as follows.

17. (Thrice Amended) A dental bleaching composition adapted for whitening and desensitizing a person's teeth, comprising:

at least one dental bleaching agent included in an amount so as to have a tooth whitening effect on a person's teeth;

potassium nitrate included in an amount of about 0.01% to about 2% by weight of the dental bleaching composition so as to result in [(i) enhanced tooth whitening by said dental bleaching agent and (ii)] reduced sensitivity that may be caused by said dental bleaching agent when the dental bleaching composition is passively maintained in contact with the person's teeth for a time period of at least about 15 minutes without brushing or scrubbing; and

a carrier that is substantially free of abrasives into which said dental bleaching agent and potassium nitrate are dispersed.

28. (Twice Amended) A dental bleaching composition for whitening and desensitizing a person's teeth comprising:

at least one dental bleaching agent included in an amount so as to have a tooth whitening effect when contacted with a person's teeth;

potassium nitrate included in an amount of about 0.01% to about 2% by weight of the dental bleaching composition so as to result in [(i) an increase in tooth whitening by said dental bleaching agent and (ii)] a reduction in sensitivity that may be caused by said dental bleaching agent when the dental bleaching composition is maintained in contact with the person's teeth for a time period of at least about 15 minutes without brushing or scrubbing; and

a carrier into which said dental bleaching agent and potassium nitrate are dispersed.